K111611
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510(k) Summary

General Provisions

Submitter:	Merit Medical Systems, Inc.
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Telephone No.:	801-208-4389
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Contact Person:	John C. Knorpp, Director, Regulatory Affairs - Endotek Division
Email:	jknorpp@merit.com
Date of Preparation:	July 18, 2011
Registration No.:	1721504

Subject Device

Trade Name:	EndoMAXX™ Fully Covered Esophageal Stent
Common/Usual Name:	Esophageal Stent
Classification Name:	Prosthesis, Esophageal

Predicate Device

Trade Name:	ALIMAXX-ES™ Esophageal Stent
Classification Name:	Prosthesis, Esophageal
Premarket Notification:	K051621 & K080838

Classification

CFR Listing:	Class II per 21 CFR 878.3610
Product Code:	ESW
Review Branch:	General & Plastic Surgery (Review Panel: Gastroenterology/Urology)

Indications for Use

The MERIT ENDOTEK™ EndoMAXX™ Fully Covered Esophageal Stent is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors and for occlusion of esophageal fistulae.

Device Description

The MERIT ENDOTEK™ EndoMAXX Fully Covered Esophageal Stent is comprised of two components: the radiopaque self-expanding Nitinol stent and the deployment catheter. The stent is completely covered with a biocompatible silicone membrane. The stent expansion results from the physical properties of the metal and the proprietary geometry. The stent is designed with a larger diameter at the distal and proximal ends to reduce the possibility of migration. The overall stent geometry is designed to minimize foreshortening upon expansion, thus facilitating improvement in deployment accuracy. The proximal and distal ends of the stent are threaded with a suture intended for use in proximal and distal repositioning of the stent. The stent is deployed with a dedicated deployment catheter. The deployment catheter consists of two coaxial sheaths attached to a deployment handle. The handle permits

one-handed positioning and deployment via a trigger mechanism. The exterior sheath serves to constrain the stent until the sheath is retracted during deployment. A radiopaque tip and marker on the inner shaft proximal to the stent aid the operator in determining stent position in relation to the deployment threshold. Once deployment is initiated, the stent cannot be reconstrained. The stent can be repositioned proximally until the first deployment trigger is deployed for a two deployment trigger device or until the second deployment trigger is deployed for a three deployment trigger device. The inner tube of the coaxial sheath catheter contains a central lumen that will accommodate a 0.035" (0.89mm) guide wire. This feature is designed to allow safe guidance of the deployment catheter to the intended implant site while minimizing the risk of esophageal injury from the deployment catheter tip.

Comparison to the Predicate

Both the subject and predicate devices are self expanding, fully covered Nitinol stents preloaded on a deployment catheter.. The EndoMAXX Stent incorporates modifications to the cover, suture and stent lattice.

Both the subject and predicate deployment catheters are user controlled, single handed mechanisms designed for endoscopic placement of the stent over a guidewire. The EndoMAXX deployment catheter has been modified to fit the EndoMAXX Stent.

Safety & Performance Testing

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, a battery of tests was performed according to protocols based on the requirements of the following documents, and were shown to meet the acceptance criteria that were determined to be applicable to the safety and efficacy of the device:

- ASTM D4169-09, Standard Practice for Performance Testing of Shipping Containers and Systems, 2009
- ASTM D-4332-01, Standard practice for conditioning containers, packages, or packaging components for testing, 2006
- ASTM F2052-06e1 Measurement of Magnetically Induced Displacement Force on Medical Devices in the MR Environment, 2006
- ASTM F2119-07, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants, 2007
- ASTM F2129-08,Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility ,2008
- ASTM F2182-09, Measurement of Radio Frequency Induced Heating Near Passive Implants During MR Imaging, 2009
- ASTM F2213-06, Method for Measurement of Magnetically Induced Torque on Passive Implants in MR Environment, 2006
- ASTM F2503-08 Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, 2008
- ASTM G71-81, Standard Guide for Conducting and Evaluating Galvanic Corrosion Tests in Electrolytes, 2009
- ISO 2233:00; Packaging - Complete, filled transport packages and unit loads - conditioning for testing
- USP34 NF29, U.S. Pharmacopeia-National Formulary (Simulated Gastric Fluid Test Solution Only)
- ISO 10993-5:2009, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-6: Biological Evaluation of Medical Devices – Tests for Local Effects after Implantation; 2007-04-15

- ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process
- ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

The following tests were successfully conducted as per *FDA Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prosthesis*, April 28, 1998:

- Deployment Testing.
- Expansion Force Testing.
- Compression Force Testing.
- Dimensional Testing.
- Corrosion Testing.
- Tensile Strength Tests.

The following list details significant testing that was successfully completed:

- Guidewire compatibility
- Distal Tip Insertion
- Stent foreshortening
- Deployment Catheter Profile
- Deployment Trigger Stroke
- Trigger safety
- Stent Deployment Force
- Stent Repositioning after partial deployment.
- Deployment Accuracy
- Stent repositioning, after full deployment
- Stent expansion and condition after deployment
- System integrity
- Radius of leading stent struts
- Stent Springback after purse stringing suture
- Compression Force Pre-fatigue
- Expansion Force Pre-fatigue
- Stent in-fold distance
- Stent in-fold force
- Stent flexibility
- Suture cutting with forceps
- Suture tensile
- Stent Fatigue
- Cover Integrity after Fatigue
- Stent Springback after Fatigue (dimensional)
- Compression Force after Fatigue
- Expansion Force after Fatigue
- Stent Tensile
- First trigger to floater tensile
- Floater to internal connector tensile
- Second trigger to internal connector tensile
- For 3-trigger device, 1st trigger to second trigger tensile
- Handle to outer support tensile
- Handle to metal hypotube and inner shaft bond tensile

- Outer shaft to internal connector bond tensile
- Outer shaft tensile
- Pod to outer shaft tensile
- Tip to inner sheath bond
- Visualize stent with fluoroscopy
- Fluoroscopic visibility of deployment catheter
- Packaging Condition
- Stent Anti-migration Strut Height
- Corrosion
- MR Compatibility

The following biocompatibility tests were successfully completed:

- Cytotoxicity
- Sensitization
- Implantation
- Sub-Chronic Toxicity

Packaging performance before and after exposure to accelerated aging and simulated shipping and handling conditions was successfully completed.

Summary of Substantial Equivalence

Based on the indications for use, design, and safety and performance test results, the subject EndoMAXX™ Fully Covered Esophageal Stent meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the ALIMAXX-ES™ Esophageal Stent manufactured by Merit Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. John C. Knorpp
Director, Regulatory Affairs
Merit Medical System, Inc.
1600 W. Merit Parkway
SOUTH JORDAN UT 84095

JUL 29 2011

Re: K111611
Trade/Device Name: EndoMAXX™ Fully Covered Esophageal Stent
Regulation Number: 21 CFR§ 878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: July 25, 2011
Received: July 26, 2011

Dear Mr. Knorpp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 Indications for Use

Indications for Use

510(k) Number (if known): K111611

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Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K111611